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AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION

*This document relates to*

JAMES CAMPBELL, et al.,

Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,  
G.D. SEARLE LLC, (FKA G.D. SEARLE & CO.),  
and MONSANTO COMPANY,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-2530-CRB

) **PFIZER INC., PHARMACIA**  
) **CORPORATION, AND G.D.**  
) **SEARLE LLC'S ANSWER TO**  
) **COMPLAINT**

) **JURY DEMAND ENDORSED**  
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as  
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (formerly known as "Monsanto Company"<sup>1</sup>)  
3 ("Pharmacia"), and G.D. Searle LLC ("Searle"), (collectively "Defendants") and file their  
4 Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as  
5 follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiffs and Decedent were  
9 prescribed or used Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only  
10 be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals  
11 the specific time periods in which Plaintiffs and Decedent were prescribed and used Celebrex®.

12 **II.**

13 **ANSWER**

14 **Response to Allegations Regarding Parties**

15 1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but  
16 deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain  
17 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United  
18 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
19 accordance with their approval by the FDA. Defendants admit that, during certain periods of  
20 time, Celebrex® were manufactured and packaged for Searle, which developed, tested,  
21 marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by  
22 healthcare providers who are by law authorized to prescribe drugs in accordance with their  
23 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used

24 \_\_\_\_\_  
25 <sup>1</sup> Plaintiffs' Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known  
26 as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933  
27 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag  
28 Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its  
name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and  
does not and has not ever designed, produced, manufactured, sold, resold or distributed Celebrex®. Given that  
Plaintiffs allege in their Complaint that Monsanto Company was involved in distributing Celebrex®, see  
PLAINTIFFS' COMPLAINT at ¶ 11, Defendants assume Plaintiffs mean to refer to 1933 Monsanto. As a result,  
Pharmacia will respond to the allegations directed at Monsanto Company.

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1 in accordance with its FDA-approved prescribing information. Defendants state that the  
2 potential effects of Celebrex® were and are adequately described in its FDA-approved  
3 prescribing information, which was at all times adequate and comported with applicable  
4 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused  
5 Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 2. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
9 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
10 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
11 and deny the remaining allegations in this paragraph of the Complaint.

12 3. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
14 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
15 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
16 and deny the remaining allegations in this paragraph of the Complaint.

17 4. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
19 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
20 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
21 and deny the remaining allegations in this paragraph of the Complaint.

22 5. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
24 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
25 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
26 and deny the remaining allegations in this paragraph of the Complaint.

27 6. Defendants are without knowledge or information sufficient to form a belief as to the  
28 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,

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1 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
2 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
3 and deny the remaining allegations in this paragraph of the Complaint.

4 7. Defendants are without knowledge or information sufficient to form a belief as to the  
5 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, citizenship,  
6 medical condition, and whether Plaintiff used Celebrex®, and, therefore, deny the same.  
7 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
8 and deny the remaining allegations in this paragraph of the Complaint.

9 8. Defendants are without knowledge or information sufficient to form a belief as to the  
10 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's and Decedent's  
11 age and citizenship, Decedent's medical condition, whether Plaintiff is the Personal  
12 Representative of Decedent's Estate, and whether Decedent used Celebrex®, and, therefore,  
13 deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff  
14 or Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
15 Complaint.

16 9. Defendants admit that Pfizer is a Delaware corporation with its principal place of  
17 business in New York. Defendants admit that, as the result of a merger in April 2003,  
18 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph  
19 of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants  
20 are without knowledge or information sufficient to form a belief as to the truth of such  
21 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of  
22 time, Pfizer marketed and co-promoted Celebrex® in the United States, including California, to  
23 be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
24 accordance with their approval by the FDA. Defendants deny the remaining allegations in this  
25 paragraph of the Complaint.

26 10. Defendants admit that Searle is a Delaware limited liability company with its principal  
27 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,  
28 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.

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1 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
2 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
3 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
4 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
5 the remaining allegations in this paragraph of the Complaint.

6 11. Defendants admit that in 1933 an entity known as Monsanto Company (“1933  
7 Monsanto”) was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of  
8 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name  
9 to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company,  
10 was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company  
11 changed its name to Monsanto Company (“2000 Monsanto”). The 2000 Monsanto is engaged  
12 in the agricultural business and does not and has not ever manufactured, marketed, sold, or  
13 distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either  
14 Searle or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed,  
15 sold, or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a  
16 proper party in this matter. Defendants deny the remaining allegations in this paragraph of the  
17 Complaint. Defendants state that the response to this paragraph of the Complaint regarding  
18 Monsanto is incorporated by reference into Defendants’ responses to each and every paragraph  
19 of the Complaint referring to Monsanto and/or Defendants.

20 12. Defendants admit that Pharmacia is a Delaware corporation with its principal place of  
21 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as  
22 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
23 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted  
24 Celebrex® in the United States, including California, to be prescribed by healthcare providers  
25 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
26 Defendants deny the remaining allegations in this paragraph of the Complaint.

**Response to Allegations Regarding Jurisdiction and Venue**

13. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny that the same. However, Defendants admit that Plaintiffs claim that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

14. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of interests and costs.

15. Defendants are without knowledge or information to form a belief as to the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny committing a tort in the State of California and deny the remaining allegations in this paragraph of the Complaint.

16. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pfizer, Pharmacia, and Searle are registered to and do business in the States of Louisiana and California. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny committing a tort in the States of California, South

1 Carolina, Arkansas, Wisconsin, Mississippi, and Minnesota, and deny the remaining allegations  
2 in this paragraph of the Complaint.

3 **Response to Allegations Regarding Interdistrict Assignment**

4 17. Defendants state that this paragraph of the Complaint contains legal contentions to  
5 which no response is required. To the extent that a response is deemed required, Defendants  
6 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.  
7 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial  
8 Panel on Multidistrict Litigation on September 6, 2005.

9 **Response to Factual Allegations**

10 18. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
12 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
13 and is safe and effective when used in accordance with its FDA-approved prescribing  
14 information. Defendants state that the potential effects of Celebrex® were and are adequately  
15 described in its FDA-approved prescribing information, which was at all times adequate and  
16 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
17 deny that Celebrex® caused Plaintiffs or Decedent injury or damage and deny the remaining  
18 allegations in this paragraph of the Complaint.

19 19. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
21 Decedent used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary  
22 case, Celebrex® was expected to reach users and consumers without substantial change from  
23 the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

24 20. Defendants are without knowledge or information sufficient to form a belief as to the  
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
26 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
27 and is safe and effective when used in accordance with its FDA-approved prescribing  
28 information. Defendants state that the potential effects of Celebrex® were and are adequately



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1 described in its FDA-approved prescribing information, which was at all times adequate and  
2 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
3 and deny the remaining allegations in this paragraph of the Complaint.

4 21. Defendants state that the allegations in this paragraph of the Complaint regarding  
5 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no  
6 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,  
7 referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the  
8 remaining allegations in this paragraph of the Complaint.

9 22. Defendants state that the allegations in this paragraph of the Complaint are not directed  
10 towards Defendants and, therefore, no response is required. To the extent that a response is  
11 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
12 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
13 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

14 23. Defendants state that the allegations in this paragraph of the Complaint are not directed  
15 towards Defendants and, therefore, no response is required. To the extent that a response is  
16 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
17 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
18 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

19 24. Defendants state that the allegations in this paragraph of the Complaint are not directed  
20 towards Defendants and, therefore, no response is required. To the extent that a response is  
21 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
22 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
23 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

24 25. Defendants state that the allegations in this paragraph of the Complaint are not directed  
25 towards Defendants and, therefore, no response is required. To the extent that a response is  
26 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
27 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
28 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.



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26. Defendants state that the allegations in this paragraph of the Complaint regarding “other pharmaceutical companies” are not directed towards Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiffs fail to provide the proper context for the remaining allegations in this paragraph and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

27. Defendants state that the allegations in this paragraph of the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

28. Defendants admit that Searle submitted a New Drug Application (“NDA”) for Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis

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1 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny  
2 the remaining allegations in this paragraph of the Complaint.

3 29. Defendants admit that Celebrex® was launched in February 1999. Defendants admit  
4 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted  
5 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
6 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
7 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,  
8 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States  
9 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
10 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe  
11 and effective when used in accordance with its FDA-approved prescribing information.  
12 Defendants state that the potential effects of Celebrex® were and are adequately described in its  
13 FDA-approved prescribing information, which was at all times adequate and comported with  
14 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
15 remaining allegations in this paragraph of the Complaint.

16 30. Defendants state that the referenced article speaks for itself and respectfully refer the  
17 Court to the article for its actual language and text. Any attempt to characterize the article is  
18 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
20 this paragraph of the Complaint.

21 31. Defendants state that the referenced article speaks for itself and respectfully refer the  
22 Court to the article for its actual language and text. Any attempt to characterize the article is  
23 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
25 this paragraph of the Complaint.

26 32. Defendants state that Celebrex® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants state that the potential effects of  
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants deny the allegations in this paragraph of the Complaint.

3 33. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint.

9 34. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA  
10 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to  
11 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,  
12 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself  
13 and respectfully refer the Court to the study for its actual language and text. Any attempt to  
14 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of  
15 the Complaint.

16 35. Defendants state that the referenced Medical Officer Review speaks for itself and  
17 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
18 attempt to characterize the Medical Officer Review is denied. Defendants state that the  
19 referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court  
20 to the Alert for Healthcare Professionals for its actual language and text. Any attempt to  
21 characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining  
22 allegations in this paragraph of the Complaint.

23 36. Defendants state that the referenced study speaks for itself and respectfully refer the  
24 Court to the study for its actual language and text. Any attempt to characterize the study is  
25 denied. Defendants state that the referenced article speaks for itself and respectfully refer the  
26 Court to the article for its actual language and text. Any attempt to characterize the article is  
27 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
28 paragraph of the Complaint.

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37. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

41. Plaintiffs fail to provide the proper context for the allegations concerning “Public Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

42. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Plaintiffs fail to provide the proper context for the allegations concerning “Public Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

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1 Defendants deny the remaining allegations in this paragraph of the Complaint.

2 43. Defendants admit that there was a clinical trial called APC. Defendants state that the  
3 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
4 language and text. Any attempt to characterize the article is denied. Defendants deny the  
5 remaining allegations in this paragraph of the Complaint.

6 44. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
7 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
8 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 45. Defendants state that the referenced Medical Officer Review speaks for itself and  
11 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
12 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
13 allegations in this paragraph of the Complaint.

14 46. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide  
15 the proper context for the allegations concerning “other Celebrex trials” contained in this  
16 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
17 form a belief as to the truth of such allegations and, therefore, deny the same. As for the  
18 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state  
19 that the referenced study speaks for itself and respectfully refer the Court to the study for its  
20 actual language and text. Any attempt to characterize the study is denied. Defendants deny the  
21 remaining allegations in this paragraph of the Complaint.

22 47. Defendants state that the referenced article speaks for itself and respectfully refer the  
23 Court to the article for its actual language and text. Any attempt to characterize the article is  
24 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 48. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the  
26 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants  
27 therefore lack sufficient information or knowledge to form a belief as to the truth of such  
28 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for

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1 themselves and respectfully refer the Court to the studies for their actual language and text.  
2 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in  
3 this paragraph of the Complaint.

4 49. Defendants state that the referenced Medical Officer Review speaks for itself and  
5 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
6 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
7 allegations in this paragraph of the Complaint.

8 50. Defendants state that allegations in this paragraph of the Complaint regarding Vioxx®  
9 in this paragraph of the Complaint are not directed toward Defendants, and therefore no  
10 response is required. To the extent that a response is deemed required, Plaintiffs fail to provide  
11 the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in  
12 this paragraph of the Complaint. Defendants therefore lack sufficient information or  
13 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
14 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
15 the study for its actual language and text. Any attempt to characterize the study is denied.  
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 51. Defendants state that allegations in this paragraph of the Complaint regarding Merck  
18 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and  
19 therefore no response is required. To the extent that a response is deemed required, Plaintiffs  
20 fail to provide the proper context for the allegations in this paragraph of the Complaint  
21 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack  
22 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
23 therefore, deny the same. Defendants state that the referenced study speaks for itself and  
24 respectfully refer the Court to the study for its actual language and text. Any attempt to  
25 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of  
26 the Complaint.

27 52. Defendants state that allegations in this paragraph of the Complaint regarding Merck  
28 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and

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1 therefore no response is required. To the extent that a response is deemed required, Plaintiffs  
2 fail to provide the proper context for the allegations in this paragraph of the Complaint  
3 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack  
4 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
5 therefore, deny the same. Defendants state that the referenced study speaks for itself and  
6 respectfully refer the Court to the study for its actual language and text. Any attempt to  
7 characterize the study is denied. Defendants state that the referenced article speaks for itself  
8 and respectfully refer the Court to the article for its actual language and text. Any attempt to  
9 characterize the article is denied. Defendants deny the remaining allegations in this paragraph  
10 of the Complaint.

11 53. Defendants state that Celebrex® was and is safe and effective when used in accordance  
12 with its FDA-approved prescribing information. Defendants deny the allegations in this  
13 paragraph of the Complaint.

14 54. Defendants state that the referenced article speaks for itself and respectfully refer the  
15 Court to the article for its actual language and text. Any attempt to characterize the article is  
16 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 55. Defendants state that allegations in this paragraph of the Complaint are not directed  
18 toward Defendants, and therefore no response is required. To the extent that a response is  
19 deemed required, Defendants state that the referenced article speaks for itself and respectfully  
20 refer the Court to the article for its actual language and text. Any attempt to characterize the  
21 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 56. Defendants deny the allegations in this paragraph of the Complaint.

23 57. Defendants state that Celebrex® was and is safe and effective when used in accordance  
24 with its FDA-approved prescribing information. Defendants state that the potential effects of  
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
26 which was at all times adequate and comported with applicable standards of care and law.  
27 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
28 remaining allegations contained in this paragraph of the Complaint.



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1 58. Defendants deny any wrongful conduct and deny the allegations contained in this  
2 paragraph of the Complaint.

3 59. Defendants deny any wrongful conduct and deny the allegations contained in this  
4 paragraph of the Complaint.

5 60. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny any wrongful conduct and deny the remaining allegations contained in this  
10 paragraph of the Complaint.

11 61. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
13 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
14 and is safe and effective when used in accordance with its FDA-approved prescribing  
15 information. Defendants state that the potential effects of Celebrex® were and are adequately  
16 described in its FDA-approved prescribing information, which was at all times adequate and  
17 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
18 deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this  
19 paragraph of the Complaint.

20 62. Defendants admit that the FDA Division of Drug Marketing, Advertising, and  
21 Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state  
22 that the referenced letter speaks for itself and respectfully refer the Court to the letter for its  
23 actual language and text. Any attempt to characterize the letter is denied. Defendants admit  
24 that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the  
25 referenced letter speaks for itself and respectfully refer the Court to the letter for its actual  
26 language and text. Any attempt to characterize the letter is denied. Defendants state that the  
27 transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and  
28 respectfully refer the Court to the transcripts for their actual language and text. Any attempt to

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1 characterize the transcripts is denied. Defendants state that the referenced study speaks for  
2 itself and respectfully refer the Court to the article for its actual language and text. Any attempt  
3 to characterize the article is denied. Defendants deny the remaining allegations in this  
4 paragraph of the Complaint.

5 63. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
10 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
11 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
12 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
13 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
14 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
15 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
16 allegations in this paragraph of the Complaint.

17 64. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
22 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
23 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
24 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
25 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
26 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
27 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a  
28 prescription medication which is approved by the FDA for the following indications: (1) for

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1 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of  
2 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the  
3 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps  
4 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic  
5 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for  
6 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age  
7 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this  
8 paragraph of the Complaint.

9 65. Defendants state that Celebrex® was and is safe and effective when used in accordance  
10 with its FDA-approved prescribing information. Defendants state that the potential effects of  
11 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
12 which at all times was adequate and comported with applicable standards of care and law.  
13 Defendants state that Plaintiffs' allegations in this paragraph of the Complaint regarding  
14 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or  
15 information to form a belief as to the truth of such allegations, and, therefore, deny the same.  
16 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
17 allegations in this paragraph of the Complaint.

18 66. Defendants state that Celebrex® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants state that the potential effects of  
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
21 which was at all times adequate and comported with applicable standards of care and law.  
22 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
23 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
24 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
25 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
26 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
27 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
28

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1 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
2 allegations in this paragraph of the Complaint.

3 67. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which at all times was adequate and comported with applicable standards of care and law.  
7 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
8 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
9 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
10 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
11 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
12 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
13 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
14 allegations in this paragraph of the Complaint.

15 68. Defendants state that Celebrex® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants state that the potential effects of  
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.  
19 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
20 the Complaint.

21 69. Defendants state that Celebrex® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants state that the potential effects of  
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
24 which was at all times adequate and comported with applicable standards of care and law.  
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
26 the Complaint.

27 70. Defendants deny the allegations in this paragraph of the Complaint.  
28

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71. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

72. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

73. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or Decedent used Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

75. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 76. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® are and were adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
8 the study for its actual language and text. Any attempt to characterize the study is denied.  
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
10 the Complaint.

11 77. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
13 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
14 and is safe and effective when used in accordance with its FDA-approved prescribing  
15 information. Defendants state that the potential effects of Celebrex® are and were adequately  
16 described in its FDA-approved prescribing information, which was at all times adequate and  
17 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
18 and deny the remaining allegations in this paragraph of the Complaint.

19 **Response to First Cause of Action: Negligence**

20 78. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
21 Complaint as if fully set forth herein.

22 79. Defendants state that this paragraph of the Complaint contains legal contentions to  
23 which no response is required. To the extent that a response is deemed required, Defendants  
24 admit that they had duties as are imposed by law but deny having breached such duties.  
25 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
26 FDA-approved prescribing information. Defendants state that the potential effects of  
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 80. Defendants state that this paragraph of the Complaint contains legal contentions to  
4 which no response is required. To the extent that a response is deemed required, Defendants  
5 admit that they had duties as are imposed by law but deny having breached such duties.  
6 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
7 FDA-approved prescribing information. Defendants state that the potential effects of  
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
11 the Complaint.

12 81. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
14 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
15 and is safe and effective when used in accordance with its FDA-approved prescribing  
16 information. Defendants state that the potential effects of Celebrex® were and are adequately  
17 described in its FDA-approved prescribing information, which was at all times adequate and  
18 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
19 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

20 82. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
22 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
23 and is safe and effective when used in accordance with its FDA-approved prescribing  
24 information. Defendants state that the potential effects of Celebrex® were and are adequately  
25 described in its FDA-approved prescribing information, which was at all times adequate and  
26 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
27 and deny the remaining allegations in this paragraph of the Complaint.

28



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1 83. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 84. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
9 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
10 and is safe and effective when used in accordance with its FDA-approved prescribing  
11 information. Defendants state that the potential effects of Celebrex® were and are adequately  
12 described in its FDA-approved prescribing information, which was at all times adequate and  
13 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
14 deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining  
15 allegations in this paragraph of the Complaint.

16 85. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
18 Decedent used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful  
19 conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the  
20 remaining allegations in this paragraph of the Complaint.

21 86. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
22 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
23 Complaint.

24 87. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
25 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
26 Complaint.

**Response to Second Cause of Action: Strict Liability**

88. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

89. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or Decedent used Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

90. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

91. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the remaining allegations in this paragraph of the Complaint.

92. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the  
4 remaining allegations in this paragraph of the Complaint, including all subparts.

5 93. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny that Celebrex® is unreasonably dangerous and deny the remaining allegations  
10 in this paragraph of the Complaint.

11 94. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
13 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
14 and is safe and effective when used in accordance with its FDA-approved prescribing  
15 information. Defendants state that the potential effects of Celebrex® were and are adequately  
16 described in its FDA-approved prescribing information, which was at all times adequate and  
17 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
18 deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs or Decedent injury or  
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 95. Defendants state that Celebrex® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
25 remaining allegations in this paragraph of the Complaint.

26 96. Defendants are without knowledge or information sufficient to form a belief as to the  
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
28 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was

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1 and is safe and effective when used in accordance with its FDA-approved prescribing  
2 information. Defendants state that the potential effects of Celebrex® were and are adequately  
3 described in its FDA-approved prescribing information, which was at all times adequate and  
4 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
5 deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs or Decedent injury or  
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 97. Defendants state that Celebrex® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
12 the Complaint.

13 98. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
15 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
16 and is safe and effective when used in accordance with its FDA-approved prescribing  
17 information. Defendants state that the potential effects of Celebrex® were and are adequately  
18 described in its FDA-approved prescribing information, which was at all times adequate and  
19 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
20 deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining  
21 allegations in this paragraph of the Complaint.

22 99. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

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100. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

101. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

102. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

103. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Third Cause of Action: Breach of Express Warranty**

104. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

105. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided

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1 FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining  
2 allegations in this paragraph of the Complaint.

3 106. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
5 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
6 and is safe and effective when used in accordance with its FDA-approved prescribing  
7 information. Defendants state that the potential effects of Celebrex® were and are adequately  
8 described in its FDA-approved prescribing information, which was at all times adequate and  
9 comported with applicable standards of care and law. Defendants admit that they provided  
10 FDA-approved prescribing information regarding Celebrex®. Defendants deny any wrongful  
11 conduct and deny the remaining allegations in this paragraph of the Complaint, including all  
12 subparts.

13 107. Defendants admit that they provided FDA-approved prescribing information regarding  
14 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this  
15 paragraph of the Complaint.

16 108. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 109. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

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110. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or Decedent used Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

111. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

112. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

113. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Fourth Cause of Action: Breach of Implied Warranty**

114. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

115. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.



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1 116. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants admit that they provided FDA-approved prescribing information regarding  
6 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 117. Defendants state that Celebrex® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny the remaining allegations in this paragraph of the Complaint.

12 118. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
14 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
15 and is safe and effective when used in accordance with its FDA-approved prescribing  
16 information. Defendants state that the potential effects of Celebrex® were and are adequately  
17 described in its FDA-approved prescribing information, which was at all times adequate and  
18 comported with applicable standards of care and law. Defendants admit that they provided  
19 FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining  
20 allegations in this paragraph of the Complaint.

21 119. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
23 Decedent used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary  
24 case, Celebrex® was expected to reach users and consumers without substantial change from  
25 the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 120. Defendants are without knowledge or information sufficient to form a belief as to the  
27 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
28 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was

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1 and is safe and effective when used in accordance with its FDA-approved prescribing  
2 information. Defendants state that the potential effects of Celebrex® were and are adequately  
3 described in its FDA-approved prescribing information, which was at all times adequate and  
4 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
5 deny that they breached any warranty, and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 121. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
8 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
9 Complaint.

10 122. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
11 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
12 Complaint.

13 123. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
14 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
15 Complaint.

16 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

17 124. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
18 Complaint as if fully set forth herein.

19 125. Defendants state that this paragraph of the Complaint contains legal contentions to  
20 which no response is required. To the extent that a response is deemed required, Defendants  
21 admit that they had duties as are imposed by law but deny having breached such duties.  
22 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
23 FDA-approved prescribing information. Defendants state that the potential effects of  
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

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1 126. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint, including all subparts.

7 127. Defendants state that Celebrex® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
12 the Complaint.

13 128. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
15 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
16 and is safe and effective when used in accordance with its FDA-approved prescribing  
17 information. Defendants state that the potential effects of Celebrex® were and are adequately  
18 described in its FDA-approved prescribing information, which was at all times adequate and  
19 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
20 deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining  
21 allegations in this paragraph of the Complaint.

22 129. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

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1 130. Defendants are without knowledge or information sufficient to form a belief as to the  
2 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
3 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
4 and is safe and effective when used in accordance with its FDA-approved prescribing  
5 information. Defendants state that the potential effects of Celebrex® were and are adequately  
6 described in its FDA-approved prescribing information, which was at all times adequate and  
7 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
8 and deny the remaining allegations in this paragraph of the Complaint.

9 131. Defendants are without knowledge or information sufficient to form a belief as to the  
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
11 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
12 and is safe and effective when used in accordance with its FDA-approved prescribing  
13 information. Defendants state that the potential effects of Celebrex® were and are adequately  
14 described in its FDA-approved prescribing information, which was at all times adequate and  
15 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
16 and deny the remaining allegations in this paragraph of the Complaint.

17 132. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
19 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
20 and is safe and effective when used in accordance with its FDA-approved prescribing  
21 information. Defendants state that the potential effects of Celebrex® were and are adequately  
22 described in its FDA-approved prescribing information, which was at all times adequate and  
23 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
24 and deny the remaining allegations in this paragraph of the Complaint.

25 133. Defendants are without knowledge or information sufficient to form a belief as to the  
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
27 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
28 and is safe and effective when used in accordance with its FDA-approved prescribing

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1 information. Defendants state that the potential effects of Celebrex® were and are adequately  
2 described in its FDA-approved prescribing information, which was at all times adequate and  
3 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
4 and deny the remaining allegations in this paragraph of the Complaint.

5 134. Defendants are without knowledge or information sufficient to form a belief as to the  
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
7 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
8 and is safe and effective when used in accordance with its FDA-approved prescribing  
9 information. Defendants state that the potential effects of Celebrex® were and are adequately  
10 described in its FDA-approved prescribing information, which was at all times adequate and  
11 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
12 and deny the remaining allegations in this paragraph of the Complaint.

13 135. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
15 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
16 and is safe and effective when used in accordance with its FDA-approved prescribing  
17 information. Defendants state that the potential effects of Celebrex® were and are adequately  
18 described in its FDA-approved prescribing information, which was at all times adequate and  
19 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
20 and deny the remaining allegations in this paragraph of the Complaint.

21 136. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
22 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
23 Complaint.

24 137. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
25 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
26 Complaint.

1 138. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
2 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
3 Complaint.

4 **Response to Sixth Cause of Action: Unjust Enrichment**

5 139. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
6 Complaint as if fully set forth herein.

7 140. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
8 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
9 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
10 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
11 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
12 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
14 the remaining allegations in this paragraph of the Complaint.

15 141. Defendants are without knowledge or information sufficient to form a belief as to the  
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
17 Decedent used Celebrex® and, therefore, deny the same. Defendants deny the remaining  
18 allegations in this paragraph of the Complaint.

19 142. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
21 Decedent used Celebrex® and, therefore, deny the same. Defendants deny the remaining  
22 allegations in this paragraph of the Complaint.

23 143. Defendants are without knowledge or information sufficient to form a belief as to the  
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
25 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
26 and is safe and effective when used in accordance with its FDA-approved prescribing  
27 information. Defendants state that the potential effects of Celebrex® were and are adequately  
28 described in its FDA-approved prescribing information, which was at all times adequate and

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1 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
2 and deny the remaining allegations in this paragraph of the Complaint.

3 144. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
5 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
6 and is safe and effective when used in accordance with its FDA-approved prescribing  
7 information. Defendants state that the potential effects of Celebrex® were and are adequately  
8 described in its FDA-approved prescribing information, which was at all times adequate and  
9 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
10 and deny the remaining allegations in this paragraph of the Complaint.

11 145. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
12 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
13 Complaint.

14 **Response to Seventh Cause of Action: Wrongful Death**

15 146. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
16 Complaint as if fully set forth herein.

17 147. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex®  
22 caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this  
23 paragraph of the Complaint.

24 148. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
25 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
26 Complaint.



1 149. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
2 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
3 Complaint.

4 150. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
5 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
6 Complaint.

7 **Response to Eighth Cause of Action: Loss of Consortium**

8 151. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
9 Complaint as if fully set forth herein.

10 152. Defendants state that this paragraph of the Complaint contains legal contentions to  
11 which no response is required. To the extent that a response is deemed required, Defendants  
12 deny the allegations in this paragraph of the Complaint.

13 153. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding Plaintiff and Decedent's  
15 marital status, and, therefore, deny the same. Defendants deny that Celebrex® caused Plaintiff  
16 or Decedent injury or damage and deny the remaining allegations in this paragraph of the  
17 Complaint.

18 154. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
19 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
20 Complaint.

21 155. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
22 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
23 Complaint.

24 156. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
25 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
26 Complaint.

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1 **Response to Prayer for Relief**

2 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent  
3 injury or damage, and deny the remaining allegations in paragraph of the Complaint headed  
4 “Prayer for Relief,” including all subparts.

5 **III.**

6 **GENERAL DENIAL**

7 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs’  
8 Complaint that have not been previously admitted, denied, or explained.

9 **IV.**

10 **AFFIRMATIVE DEFENSES**

11 Defendants reserve the right to rely upon any of the following or additional defenses to  
12 claims asserted by Plaintiffs to the extent that such defenses are supported by information  
13 developed through discovery or evidence at trial. Defendants affirmatively show that:

14 **First Defense**

15 1. The Complaint fails to state a claim upon which relief can be granted.

16 **Second Defense**

17 2. Celebrex® is a prescription medical product. The federal government has preempted  
18 the field of law applicable to the labeling and warning of prescription medical products.  
19 Defendants’ labeling and warning of Celebrex® was at all times in compliance with applicable  
20 federal law. Plaintiffs’ causes of action against Defendants, therefore, fail to state a claim upon  
21 which relief can be granted; such claims, if allowed, would conflict with applicable federal law  
22 and violate the Supremacy Clause of the United States Constitution.

23 **Third Defense**

24 3. At all relevant times, Defendants provided proper warnings, information and  
25 instructions for the drug in accordance with generally recognized and prevailing standards in  
26 existence at the time.

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**Fourth Defense**

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

**Fifth Defense**

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

**Sixth Defense**

6. Plaintiffs' action is barred by the statute of repose.

**Seventh Defense**

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs and Decedent were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

**Eighth Defense**

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

**Ninth Defense**

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

**Tenth Defense**

10. Any injuries or expenses incurred by Plaintiffs and Decedent were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

**Eleventh Defense**

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs or Decedent.

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**Twelfth Defense**

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs’ and Decedent’s treating and prescribing physicians.

**Thirteenth Defense**

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

**Fourteenth Defense**

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

**Fifteenth Defense**

15. Plaintiffs’ causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs and Decedent was prepared in accordance with the applicable standard of care.

**Sixteenth Defense**

16. Plaintiffs’ and Decedent’s alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

**Seventeenth Defense**

17. Plaintiffs’ alleged damages were not caused by any failure to warn on the part of Defendants.

**Eighteenth Defense**

18. Plaintiffs' and Decedent's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

**Nineteenth Defense**

19. Plaintiffs and Decedent knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

**Twentieth Defense**

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

**Twenty-first Defense**

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**Twenty-second Defense**

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

**Twenty-third Defense**

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

**Twenty-fourth Defense**

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

**Twenty-fifth Defense**

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

**Twenty-sixth Defense**

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

**Twenty-seventh Defense**

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

**Twenty-eighth Defense**

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

**Twenty-ninth Defense**

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

**Thirtieth Defense**

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of South Carolina, Arkansas, Wisconsin, Mississippi, and Minnesota, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

**Thirty-first Defense**

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

**Thirty-second Defense**

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

**Thirty-third Defense**

33. Plaintiffs' punitive damage claims are preempted by federal law.

**Thirty-fourth Defense**

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

**Thirty-fifth Defense**

35. Plaintiffs and Decedent failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

**Thirty-sixth Defense**

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

**Thirty-seventh Defense**

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

**Thirty-eighth Defense**

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of South Carolina, Arkansas, Wisconsin,



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Mississippi, and Minnesota. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs or Decedent; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs or Decedent and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

#### **Thirty-ninth Defense**

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

#### **Fortieth Defense**

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

**Forty-first Defense**

41. If Plaintiffs and Decedent have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

**Forty-second Defense**

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

**Forty-third Defense**

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

**Forty-fourth Defense**

44. Plaintiffs' claims are barred because Plaintiffs' and Decedent's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs and Decedent, and were independent of or far removed from Defendants' conduct.

**Forty-fifth Defense**

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs and Decedent.

**Forty-sixth Defense**

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs and Decedent did not incur any ascertainable loss as a result of Defendants' conduct.

**Forty-seventh Defense**

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by

any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

**Forty-eighth Defense**

48. The claims must be dismissed because Plaintiffs and Decedent would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

**Forty-ninth Defense**

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

**Fiftieth Defense**

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

**Fifty-first Defense**

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs and Decedent.

**Fifty-second Defense**

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

**Fifty-third Defense**

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations,

1 and with the specific determinations by FDA specifying the language that should be used in the  
2 labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the  
3 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the  
4 United States.

5 **Fifty-fourth Defense**

6 54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity  
7 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

8 **Fifty-fifth Defense**

9 55. Defendants state on information and belief that the Complaint and each purported cause  
10 of action contained therein is barred by the statutes of limitations contained in California Code  
11 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation  
12 as may apply.

13 **Fifty-sixth Defense**

14 56. Defendants state on information and belief that any injuries, losses, or damages suffered  
15 by Plaintiffs and Decedent were proximately caused, in whole or in part, by the negligence or  
16 other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs'  
17 recovery against Defendants, if any, should be reduced pursuant to California Civil Code §  
18 1431.2.

19 **Fifty-seventh Defense**

20 57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of  
21 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil  
22 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive  
23 damages is also barred under California Civil Code § 3294(b).

24 **Fifty-eighth Defense**

25 58. Plaintiffs' claims are barred, in whole or in part, pursuant to South Carolina Code Ann.  
26 § 15-3-20.

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**Fifty-ninth Defense**

59. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Rule 9 of the Arkansas Rules of Civil Procedure, and should be dismissed.

**Sixtieth Defense**

60. Any claims for breach of warranty are barred for lack of reasonable reliance, lack of timely notice, lack of privity, and because the alleged warranties were excluded and/or disclaimed.

**Sixty-first Defense**

61. Plaintiffs' claims are barred and/or limited by the provisions of the Arkansas Products Liability Act, Ark. Code Ann. § 16-116-101, et seq.

**Sixty-second Defense**

62. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Arkansas Civil Justice Reform Act of 2003, Ark. Code Ann. § 16-55-201 et seq.

**Sixty-third Defense**

63. To the extent that Plaintiffs rely upon any theory of breach of warranty, Plaintiffs' claims are barred because Defendants did not make or breach any express or implied warranties, Plaintiffs and Decedent failed to give reasonable notice to Defendants of any alleged breach or breaches of warranty as required by Miss. Code Ann § 75-2-607(3)(a).

**Sixty-fourth Defense**

64. Any verdict or judgment rendered against Defendants must be reduced under the laws of the State of Mississippi by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiffs and Decedent, such as insurance, social security, worker's compensation, or employee benefits programs. Plaintiffs and Decedent may have settled their claims for alleged injuries and damages with certain parties. Defendants therefore are, in any event, entitled to a credit in the amount of any such settlement heretofore made between Plaintiffs or Decedent and any such parties.

**Sixty-fifth Defense**

65. Plaintiffs' claims for punitive damages are limited or barred by the standards governing

1 exemplary damage awards which arise under the United States Constitution and decisions of  
2 the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589  
3 (1996); *Cooper Industries, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and  
4 *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi  
5 Constitution, statutes, and decisions of Mississippi courts.

6 **Sixty-sixth Defense**

7 66. Defendants assert that Plaintiffs' claim for punitive damages is governed and limited by  
8 Miss. Code Ann. § 11-1-65, and Defendants hereby plead and invoke the provisions of the  
9 same.

10 **Sixty-seventh Defense**

11 67. Celebrex® and the Defendants' actions conformed to the state of the art medical and  
12 scientific knowledge at all times relevant to this lawsuit and Celebrex® complied with  
13 applicable product safety statutes and regulations as described in Restatement (Third) of Torts:  
14 Products Liability § 4.

15 **Sixty-eighth Defense**

16 68. Defendants satisfied their duty to warn under the learned intermediary doctrine and  
17 Plaintiffs' claims are therefore barred.

18 **Sixty-ninth Defense**

19 69. Defendants hereby plead all defenses contained in Miss. Code Ann. § 11-1-63 and  
20 hereby invoke the provisions of Miss. Code Ann. § 85-5-7.

21 **Seventieth Defense**

22 70. Plaintiffs failed to join all indispensable parties; as a result of such failure to join,  
23 complete relief cannot be accorded to those already parties to the action and will result in  
24 prejudice to Defendants in any possible future litigation.

25 **Seventy-first Defense**

26 71. Any judicially-created definitions of manufacturing defect and design defect, and  
27 standards for determining whether there has been an actionable failure to ward, are  
28 unconstitutional in that, among other things, they are void for vagueness and undue burden on

interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.

### **Seventy-second Defense**

72. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical products at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

### **Seventy-third Defense**

73. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any award of punitive damages is barred.

### **Seventy-fourth Defense**

74. Plaintiffs' claims are barred in whole or in part because Plaintiffs lack standing to bring such claims.

### **Seventy-fifth Defense**

75. Plaintiff's claims for punitive damages are subject to all provisions of Minnesota law, including but not limited to Minnesota Statute 549.191.

### **Seventy-sixth Defense**

76. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

**V.**

### **PRAYER**

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' and Decedent's alleged injuries, losses or damages is attributable to each person;



1 5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater  
2 than an amount which equals their proportionate share, if any, of the total fault or other  
3 liability which proximately caused Plaintiffs' and Decedent's injuries and damages; and

4 6. That Defendants have such other and further relief as the Court deems appropriate.

5  
6 September 14, 2007

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**JURY DEMAND**

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

September 14, 2007

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